UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

MSP CORPORATION, a Minnesota corporation,

Plaintiff,

vs.

WESTECH INSTRUMENTS, INC., a Georgia corporation; WESTECH INSTRUMENT SERVICES LTD., a United Kingdom corporation; and WESTECH INSTRUMENT HOLDINGS, PLC, a United Kingdom corporation,

Defendants.

Civil No. 07-CV-2301 (MJD/SRN)

PLAINTIFF'S MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I. INTRODUCTION

This case concerns a competitor's announced launch of a product that is the mirror image of Plaintiff's product, including the product's distinctive shape, color, design, and name, guaranteeing consumer confusion as to the source or affiliation of the imitation product. Worse, the copycat product is touted with literally false and misleading statements designed to lead consumers to falsely believe that the copycat product is endorsed by an industry consortium. This is precisely the situation for which preliminary injunctive relief is appropriate.

Plaintiff MSP Corporation ("MSP") developed a product named the "Next Generation Impactor," or "NGI," an innovative device used to measure the dose and particle size of medications dispensed through metered-dose and dry-powder inhalers.

MSP's NGI device substantially improved the accuracy, efficiency, reproducibility, and productivity of the measurement process. Due in large part to its accuracy, MSP's impactor has become the impactor of choice for companies that manufacture inhaled medicines.

In 2000, MSP introduced the NGI device with distinctive features to differentiate the device from other impactors. These features included the "Next Generation" and "NGI" names, the use of chrome and royal-blue colors on the product, and an unusual, striking puzzle-piece shape. A consortium of 15 leading pharmaceutical companies tested and approved MSP's new impactor, granting it a seal of approval that significantly enhances the impactor's standing in the market.

Defendants (collectively "Westech") recently announced that they have developed an impactor to compete against MSP's Next Generation Impactor device. To MSP's surprise, Westech copied virtually every detail of the appearance of MSP's NGI, including the shape, coloring, and even the name of MSP's product:

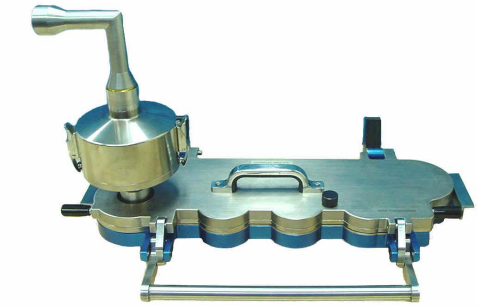

FIG. 1: MSP NGI Device

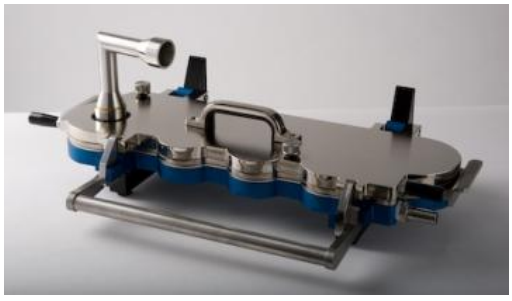

FIG. 2: Westech Impactor

As these pictures illustrate, Westech's impactor is visually indistinguishable from MSP's impactor. Not content merely to misappropriate MSP's distinctive product appearance, Westech has falsely claimed that its impactor has been somehow approved by the same pharmaceutical consortium that approved MSP's device. See *infra* page 22-23.

Westech's blatant misappropriation of MSP's trademarks and trade dress, as well as its patently false advertising violates federal and state law. There can be no question that such conduct irreparably harms MSP and justifies issuance of preliminary injunctive relief.

II. FACTS

A. MSP

MSP was founded in 1985 by University of Minnesota engineering professors Benjamin Liu and Virgil Marple. Affidavit of Daryl Roberts at ¶ 2 ("Roberts Aff."). Located in Shoreview, Minnesota, MSP focuses on cutting edge products relating to aerosols and air particles. Id. MSP's work has led to numerous innovative and patented products used by the semiconductor, pollution control, and pharmaceutical industries. Id. at ¶ 3. See also Ex. 1 at 1-1. MSP has an international reputation for achieving groundbreaking technical solutions to difficult problems in aerosol/particle technologies. MSP's products are sold around the world. Roberts Aff.at ¶¶ 3-4; Declaration of Nicholas C. Miller at ¶ 3 ("Miller Dec'l"); Declaration of Thomas Lanz at ¶ 2 ("Lanz Dec'l"). With a reputation for quality, reliability, and user-friendly products, MSP has steadily grown. It now has 40 employees. Roberts Aff. at ¶¶ 3-4.

B. Westech

Westech markets and manufactures impactors, among other aerosol testing devices. Ex. 2 at 2-1. As such, Westech competes against MSP. Previously, Westech was authorized to distribute certain MSP products, but that relationship has terminated. Roberts Aff. at ¶ 22.

Westech Instruments, Inc. serves as the United States distributor for Westech products. Ex. 2 at 2-3-4. It promotes its products in the United States and Minnesota through the Internet. Id. Westech also markets directly to Minnesota residents through direct email advertisements. Miller Dec'l at ¶ 10.

C. MSP Develops Radical New Impactor: The Next Generation Impactor Device

Various inhaled medicines, such as asthma medications, are dispensed through aerosol or powder inhalers. To develop and manufacture metered-dose and dry-powder inhalers, pharmaceutical companies must have the ability to measure the quantity and particle size of the medication dispensed by each dose. Id. at ¶ 5. Statistical monitoring of the quantity and particle size of the medication delivered by each "puff" of the inhaler is essential to the safe manufacture of an efficacious inhaler and to the development of new inhalers for commercial sale. Id.

An impactor is a device that measures the size of aerosol particles. Pharmaceutical companies use impactors to test inhalers. Id. at ¶ 6. Throughout the 1990's, pharmaceutical companies relied on impactor technology developed for military applications in the 1940's. Id. Not surprisingly, the 40's-era impactor, called the

Andersen Impactor, suffered from a lack of precision. Id.; Lanz Dec'l at ¶ 4; Miller Dec'l at ¶ 2. The Andersen Impactor forces the aerosol or powder through a series of stages (or "cascades") designed to sort particles by size: the largest particles collect in the first stage, and the smallest particles proceed to the final stage. This process can fail to sort particles with perfect accuracy. Roberts Aff. at ¶¶ 6-8; Miller Dec'l at ¶ 2. Additionally, different versions of the Andersen Impactor led to variable measurements between devices, causing invalidation of test results, FDA scrutiny of measurement procedures, and regulatory delay for drug approvals. Roberts Aff. at ¶ 6-8; Miller Dec'l at ¶ 2.

Given the dramatic need to upgrade the technology, a group of 15 pharmaceutical companies formed a consortium to fund research and development of a new impactor. Roberts Aff. at ¶ 9; Miller Dec'l at ¶ 2. The consortium called itself the Next Generation Impactor Consortium ("the Consortium"). Due to MSP's well-known expertise in aerosols and particle measurement, the Consortium selected it to develop a new impactor capable of meeting the Consortium's needs and specifications. Roberts Aff. at ¶ 10; Miller Dec'l at ¶ 2-3. After two years of intensive research and development, MSP introduced a successful prototype of the new impactor in 2000. MSP's device was named the "Next Generation Impactor" or "NGI." Roberts Aff. at ¶ 11.

The NGI device dramatically improved the reliability, accuracy, and efficiency of the particle measurement process.[1] Id. at ¶ 11. Moreover, unlike the Andersen Impactor's vertical, cylindrical design (see Ex. 4), MSP set the cascade stages in a flat, horizontal design:

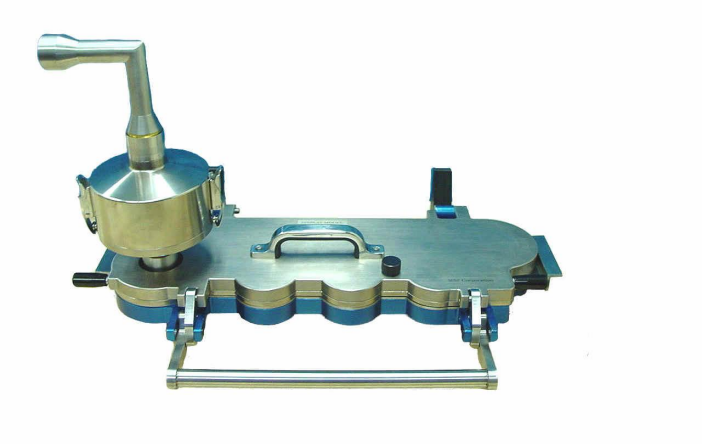

FIG. 3: MSP NGI Device

FIG. 4: Andersen Impactor

See Ex. 3 at 3-1 and 4. Determined to develop a compelling appearance for such an innovative product, MSP rejected the most simple, obvious choice -- a common rectangle or square. Instead, MSP created a unique, distinctive puzzle-piece shape for the device. Roberts Aff. at ¶ 15. This shape has no impact on the device's performance. Id.

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[1] The NGI device's technical innovations include:

(1) cups with tear-drop shapes, seals, and passageways that minimize stage overlap and perfect the sorting of particles by size;
(2) a patented pre-separator that separates active drug particles from inactive "carrier" particles prior to entry into the impactor;
(3) patented nozzles, with precise and fixed placements, to control airflow through the impactor; and
(4) a "micro-orifice collector" that functions as the final stage and collects the tiniest particles without the need of the Andersen Impactor's fibrous filter.

Roberts Aff. at ¶ 11.

Another aspect of the NGI device's unique appearance is the combination of chrome and royal blue.

The Consortium extensively tested MSP's device before approving it and concluding that it fulfills the need for a standard-setting measurement device. Roberts Aff. at ¶ 12; Lanz Dec'l at ¶ 5; Miller Dec'l at ¶ 5. The design and testing results of the NGI device were published in peer-reviewed journals. See Ex. 5 and 6. The FDA now accepts measurements taken with the NGI device as accurate and reliable. Roberts Aff. at ¶ 12; Miller Dec'l at ¶ 6. As a result, MSP has sold more than 400 NGI devices to dozens of customers around the world. Roberts Aff. at ¶ 13. Because the NGI is so dramatically superior to the Andersen Impactor, virtually all new impactors purchased by pharmaceutical companies are MSP's NGI device. Id.; Lanz Dec'l at ¶ 6; Miller Dec'l at ¶ 7.

D. MSP Uses A Distinctive Color And Shape To Stand Out In The Impactor Industry

MSP uses "NGI" and "Next Generation" as trade names for its impactor. The names identify only one device in the industry: the one that MSP promotes and sells. Ex. 7 and 8; Roberts Aff. at ¶ 15. MSP has used these names since it introduced its new impactor in 2000. The industry recognizes that these names are associated exclusively with MSP. Miller Dec'l at ¶ 9; Lanz Dec'l at ¶ 7; Roberts Aff. at ¶ 15. Understanding the trademark significance of these names, the United States Pharmacopeia describes the new impactor merely as "Apparatus 5" but notes that it "is available as the Next Generation Pharmaceutical Impactor from MSP Corporation, Minneapolis, MN." Ex. 9-

17.[2] Of course, the NGI and Next Generation Impactor names also serve to remind consumers that the MSP device has been tested and approved by the Next Generation Impactor Consortium, a valuable seal of approval from the industry. Roberts Aff. at ¶¶ 14, 16; Miller Dec'l at ¶ 9; Lanz Dec'l at ¶ 5.

MSP also distinguishes its new impactor through its unusual color and shape. Miller Dec'l at ¶ 9; Lanz Dec'l at ¶ 7; Roberts Aff. at ¶ 15. Since its introduction to the market, the NGI device has always had a chrome-colored top and a royal-blue bottom. The royal-blue coloring coordinates with MSP's royal blue corporate logo and marketing materials. See, e.g., Ex. 1. The NGI device's distinctive puzzle-piece shape also serves as a source identifier. Ex. 8 at 8-1.

Neither the coloring nor the external shape of the NGI device has any functional purpose. Roberts Aff. at ¶ 15; Lanz Dec'l at ¶ 7. Instead, the color and shape serve as trademarks and trade dress by identifying the NGI device as originating from MSP. Roberts Aff. at ¶ 16; Miller Dec'l at ¶ 9; Lanz Dec'l at ¶ 7. MSP could have chosen any color for the NGI device's external surface, and the chrome and royal-blue color scheme has no impact on functionality. Likewise, the external puzzle-piece shape does not contribute to the NGI device's functionality in any way. Roberts Aff. at ¶ 15. The NGI could be manufactured, at less expense, with a box, rectangle, or other shape. Id. Early

[2] The United States Pharmacopeia (USP) is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. See U.S. Pharmacopeia Website, http://www.usp.org/aboutUSP/ (last visited June 11, 2007).

iterations of the NGI device were rectangular. Roberts Aff. at ¶ 15; Ex. 10. Instead, MSP arbitrarily chose to machine the device into its existing shape to set it apart as an innovative new product that originates from MSP. Id.

E. Westech Copies MSP's NGI Appearance

MSP first learned of Westech's intention to launch a competing impactor in January 2007 when Westech requested a meeting between the parties. Roberts Aff. at ¶ 18. Two Westech employees traveled to Minnesota to meet with MSP officials, including MSP's co-founders, on January 24, 2007. Id. At that meeting, Westech explained that it was considering development of an impactor that would compete with the NGI. Westech did not disclose that it had already developed the impactor, much less show its impactor to MSP. Id.

Westech sent a February 5, 2007, letter to MSP purporting to summarize "the agreements" that the parties reached at the meeting. Ex. 11. In an amazing feat of creative writing, the letter asserted that MSP had no objection to Westech's rival impactor; that MSP would not pursue any claims against Westech related to the impactor; that MSP would consent to Westech's marketing efforts; and that MSP would explore licensing agreements with Westech. Id.; Roberts Aff. at ¶ 19. MSP never made any such representations at the meeting and immediately responded to Westech's work of fiction by denying that any such agreements had ever been reached, let alone discussed. Ex. 12; Roberts Aff. at ¶ 19.

MSP first saw pictures of Westech's copycat device in April 2007. Roberts Aff. at ¶ 20. Incredibly, Westech designed its device to be visually indistinguishable from the

real NGI device—the shape, colors, and appearance of Westech's knockoff are identical in virtually every respect. Ex. 13 and 14. Virtually every exterior design detail of the NGI device was copied, down to the handles, latches, and placement of component parts. Roberts Aff. at ¶ 20; Miller Dec'l at ¶ 10; Lanz Dec'l at ¶ 9. Even the individuals who helped to develop and sell the real NGI device have a difficult time distinguishing it from Westech's imitation. Id.

To further mislead consumers, Westech refers to its impactor as a "Next Generation Impactor" or "NGI" in product promotions. Ex. 13 and 15. Worse still, Westech's promotional literature misrepresents the origin of its impactor by asserting that the Consortium tested and approved the Westech impactor. As of April 12, Westech's website stated:

> Westech Next Generation Impactor (WNGI) NEW 7-stage Horizontal Cascade Impactor with final Micro-Orifice Collector, USP Apparatus 5 & 6 and EP Apparatus E
>
> ***Our new NGI*** is a precision machined instrument designed and used to separate and collect solid or liquid aerosol particulates using inertial impaction and a constant vacuum flow rate. The lateral layout for collection and orientation allows easier setup and higher throughput when compared to the more traditional vertical designs. The Next Generation Cascade Impactor Consortium organized and formulated the need for improvements to traditional physical test instruments related to inhalation drug aerosol classification. ***The fifteen pharmaceutical companies were involved with design and qualification of the new instrument called the Next Generation Cascade Impactor (NGI)***. ***As another validated instrument for inhalation drug and device testing, the NGI*** fulfills many needs in evaluations with advanced features.

Ex. 13 (emphasis added); Roberts Aff. at ¶ 20. Contrary to the assertion of this website, the Consortium has never tested or approved Westech's impactor. Roberts Aff. at ¶ 22;

Miller Dec'l at ¶¶ 11-12; Lanz Dec'l at ¶¶ 10-11. Thus, in addition to misappropriating the name, shape, design, and color of MSP's NGI device, Westech has used false advertising to misappropriate its history.

F. Likelihood of Confusion Arises In The Market

Customers have no ability to distinguish MSP's NGI device from Westech's imitation. Roberts Aff. at ¶ 22; Miller Dec'l at ¶¶ 11-12; Lanz Dec'l at ¶¶ 10-12. The visual confusion is made worse by Westech's use of the "NGI" and "Next Generation" names and its false invocation of the Consortium as an endorsing organization.

The fact that MSP sells its products through third-party distributors compounds the risk of consumer confusion. Roberts Aff. at ¶ 22; Lanz Dec'l at ¶ 11. Generally lacking direct relationships with MSP, many customers are unlikely to know whether they are purchasing the real NGI device or an imitation from a vendor. Id. Indeed, Westech distributes many medical devices manufactured by other companies. A company purchasing Westech's fake device may believe it is a real NGI device made by MSP, and that Westech is an authorized distributor of this device. Roberts Aff. at ¶ 22. Many purchasers requiring an impactor for pharmaceutical uses are small or mid-size companies without the knowledge and experience to know that Westech is marketing an imitation of MSP's NGI device. Id.; Lanz Dec'l at ¶ 11

Given this backdrop, it should not be surprising that Westech has, in fact, confused consumers. After the Westech impactor product launch in April 2007, many customers assumed that it was the real NGI device and that Westech is now an authorized

distributor of it. Id. Both MSP and its only authorized distributor have fielded questions from customers wondering whether Westech is authorized to sell MSP's NGI device. Id.

G. Consequences of Westech's Misconduct

Westech's conduct is likely to harm both MSP and the companies that rely on MSP's NGI Impactor. By confusing customers and trafficking in MSP's good name and reputation, Westech threatens to undermine MSP's reputation for selling reliable, accurate, and uniform impactors. Roberts Aff. at ¶¶ 22-26; Miller Dec'l at ¶¶ 11-12; Lanz Dec'l at ¶¶ 10-12. MSP risks having its device associated with Westech and any shortcomings of its imitation device, including device failures, manufacturing, and quality issues.

The NGI device provides a uniform and consistent measurement tool for aerosol and powder inhalers. Id. Westech's impactor includes features that MSP intentionally excluded from the NGI device because those features can undermine the accuracy and reliability of the device. For example, the Consortium rejected inclusion of removable and adjustable nozzles in the NGI device, features that Westech has included in its imitation product. Roberts Aff. at ¶ 23. This design can introduce variability into a measurement process that demands absolute precision. Id. Thus, the false sale of the Westech device as the same as the NGI, or endorsed by MSP or the Consortium, undermines consumer reliance on the qualities expected from the MSP device. Customers choose impactors that perform to precise standards, standards met by MSP's NGI device. Any deviation can ruin data collection, call test results into question, and result in regulatory delays. Id. at ¶ 24. Customers deserve to know what they are buying

and whether it is approved by the Consortium. Westech's scheme threatens to undermine the confidence that researchers, consumers, and government regulators have in the real NGI device, a result that risks a return to invalidation of data and regulatory delays. Roberts Aff. at ¶¶ 22-26; Miller Dec'l at ¶¶ 11-12; Lanz Dec'l at ¶¶ 10-12.

III. ARGUMENT

Under Eighth Circuit law, courts consider the following factors in deciding whether to issue a preliminary injunction:

> (1) the threat of irreparable harm to the movant; (2) the state of balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that movant will succeed on the merits; and (4) the public interest.

Dataphase Sys., Inc. v. C.L. Sys., Inc., 640 F.2d 109, 113 (8th Cir. 1981) (*en banc*). The law presumes that trademark infringement or false advertising irreparably harms the victim, see, e.g., Coca-Cola Co. v. Purdy, 382 F.3d 774, 789 (8th Cir. 2004), and the blatant, willful, and complete nature of Westech's infringement and deceit indicate that the remaining factors necessitate a preliminary injunction.

A. MSP WILL SUCCEED ON THE MERITS OF ITS CLAIMS

The Lanham Act prohibits the sale of products in a misleading or false manner. In particular, it imposes liability for using:

> in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which--
>
> **(A)** is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with

> another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or
>
> **(B)** in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities. . . .

15 U.S.C. § 1125(a). Westech copied the entire appearance of MSP's NGI device, made a visually identical device, and then passed it off as the real thing. Westech's scheme violates the Lanham Act by: 1) infringing MSP's trademarks in the NGI and Next Generation Impactor names, as well as the design of the device; 2) infringing MSP's distinctive trade dress for the NGI device; and 3) falsely promoting Westech's device as a device approved by the Consortium. MSP is likely to prevail on each of these claims.[3]

1. Westech Has Infringed MSP's Trademarks

Trademark infringement is established if: 1) MSP possesses valid trademarks; and 2) Westech's infringing marks are likely to be confused with MSP's marks. See, e.g., Aveda Corp. v. Evita Mktg., Inc., 706 F. Supp. 1419, 1426 (D. Minn. 1989).

MSP unquestionably possesses valid trademarks in the "NGI" and "Next Generation" names. To possess a valid trademark, one must simply use the mark in actual commerce to identify goods and be the first to do so. Id. at 1427. Until Westech marketed its infringing product, MSP's device was the first and only impactor marked by

[3] MSP's Complaint also includes claims under Minnesota common law and theDeceptive Trade Practices Act, Minn. § 325D.44. MSP's likelihood of prevailing on its Lanham Act claims also demonstrates that it will likely prevail on the claims under Minnesota law. See DeRosier v. 5931 Business Trust, 870 F. Supp. 941, 948 (D. Minn. 1994) (equating the claims under Minnesota common law, the Lanham Act, 15 U.S.C. § 1125, and the Minnesota Deceptive Trade Practices Act, Minn. Stat. § 325D.44.).

the NGI and Next Generation names. MSP used the marks to identify its impactor as its product and as the only one that has been endorsed by the Consortium.

Similarly, MSP has trademark rights in the chrome and royal-blue color scheme for impactors and the novel puzzle-piece device shape. See Qualitex v. Jacobson Prods. Co., 514 U.S. 159, 162, 164 (1995) (holding that product color and shape can be valid trademark); Master Distribs., Inc. v. Pako Corp., 986 F.2d 219, 224 (8th Cir. 1993) ("Moreover, when Congress broadened the definition of trademark in 1988, three years after Owens-Corning was decided, it 'intentionally retain[ed] ... the words 'symbol or device' so as not to preclude the registration of colors, shapes, sounds or configurations where they function as trademarks.'") (citing S.Rep. No. 100-515, 100th Cong., 2d Sess. 44 (1988), *reprinted in* 1988 U.S.C.C.A.N. 5577, 5607); Animal Fair, Inc. v. AMFESCO Indus., Inc., 620 F. Supp. 175, 190 (D. Minn. 1985) (relying on fact that Patent and Trademark Office permits registration of inherently distinctive product shapes without any further showing of secondary meaning) (citing 1 J. McCarthy, Trademarks and Unfair Competition, § 7:31 at 263 (2d ed. 1984)). Neither the external puzzle-piece shape nor color have any relationship to the impactor's functionality. See Roberts Aff. at ¶ 15. The shape of the NGI device is particularly distinctive, and MSP specifically chose to take the trouble of adopting an "artistic" design for the NGI device because many of its products are identified by a similarly unique flair. Id.

Westech's copycat device has created an obvious likelihood that consumers will be confused as to the sponsorship of the device. Westech's wholesale appropriation of every distinguishing feature of MSP's NGI device leaves little doubt that consumers may

mistake the origin of the Westech impactors that have been seen or purchased. This Court considers several factors in evaluating the likelihood that consumers will be confused by similar marks:

> A likelihood of confusion exists if an appreciable number of reasonable buyers are likely to be confused by the similar marks. Resolution of this issue depends on consideration of:
>
> > (1) the strength of the infringed mark;
> > (2) whether the marks, examined as a whole, are similar;
> > (3) the degree to which the products compete with each other;
> > (4) intent on the part of the alleged infringer to pass off its goods as the product of another;
> > (5) evidence of actual confusion;
> > (6) whether the kind of product, its cost and conditions of purchase, allow the purchaser to eliminate the likelihood of confusion which would otherwise exist.

Aveda Corp., 706 F. Supp. at 1427-28 (internal citations omitted). A simple comparison of the devices demonstrates that Westech has designed its impostor to be indistinguishable from the real NGI device. While the eyeball test alone indicates a likelihood of consumer confusion, each of the enumerated factors confirms that conclusion.

MSP's trademarks are strong. The NGI and Next Generation names, color scheme, and shape have been used exclusively since introduction of MSP's impactor in 2000. All NGI devices have been sold with these marks. Roberts Aff. at ¶¶ 15-16. Because the NGI device revolutionized impactor technology and is unique in the industry, MSP's marks are inextricably linked with MSP. See, e.g., Ex. 7. MSP has extensively advertised and promoted the distinctive NGI device since the product was introduced to the market. Lanz Dec'l at ¶ 3; Roberts Aff. at ¶ 16. The NGI device has

been extraordinarily well-received and is well-recognized by customers. See Insty*Bit, Inc. v. Poly-Tech Indus., Inc., 95 F.3d 663, 670 (8th Cir. 1996) (citing favorable reviews of and knowledge of the device as evidence of strength of marks); Lanz Dec'l at ¶ 4; Miller Dec'l at ¶ 6-9.

Far beyond mere similarity, Westech's marks are identical to MSP's marks. Westech has employed the NGI and Next Generation names in its advertisements, copied the precise shape of MSP's impactor, and even combined the same shade of blue with chrome in the same color layout. Westech's infringement of any one of MSP's marks would have created similarity between the products. With its wholesale taking of all of MSP's marks, the result is a visual identity that compels a conclusion of likelihood of confusion.

Westech's direct competition with MSP further increases the likelihood of consumer confusion. Westech's impactor directly competes with the NGI device for the same consumers. See Miller Dec'l at ¶ 10; Lanz Dec'l at ¶ 12. Other than the outdated Andersen Impactor, Westech's impactor is the only product to compete with the NGI device. MSP's reliance on third-party distributors for the NGI device also increases the likelihood of consumer confusion. Most NGI devices are sold by distributors so customers often have no direct relationship or contact with MSP. See Roberts Aff. at ¶ 22. In the past, Westech has itself distributed other products manufactured by MSP. As a result, a consumer could easily purchase a Westech impactor from a distributor, or even Westech itself, mistakenly believing that it is purchasing an NGI device from an authorized distributor. See Sun-Fun Prods., Inc. v. Suntan Research & Dev. Inc., 656

F.2d 186, 191 (5th Cir. 1981) (relying on evidence of past supplier-distributor relationship to find likelihood of confusion). Because the NGI device has been the only impactor of its kind for six years, consumers likely have no knowledge that an impostor exists.[4]

Rather than choosing to compete on the merits by presenting consumers with an honest choice, Westech copied MSP's product with a name and appearance that are entirely unrelated to functionality. Westech's wholesale misappropriation of the NGI device's name, puzzle-piece shape, and color scheme warrants an inference that Westech intended to mislead consumers, further tilting the balance of factors to a finding of likelihood of confusion. See, e.g., Insty*Bit, Inc., 95 F.3d at 671 (relying on failure of defendant to distinguish its product with easy design changes as evidence of intent to mislead). Wrongful intent can also be inferred from Westech's prior role as an MSP distributor; Westech's underhanded attempt to obtain MSP's approval for its imitation (while declining to show MSP what it looks like); and Westech's false claims that its impactor has been approved by the Consortium. See id. (relying on fact that defendant previously distributed plaintiff's products); Perfumania, Inc. v. Perfulandia, Inc., 279 F.

[4] Although the purchasers of pharmaceutical impactors are not unsophisticated, the expertise, knowledge, and sophistication of consumers does not always ensure the absence of confusion. See Gilbert/Robinson, Inc. v. Carrie Beverage-Missouri, Inc., 758 F. Supp. 512, 524 (E.D. Mo. 1991) (expertise of the purchasers does not always assure the absence of confusion) (citing Induct-O-Matic Corp. v. Inductotherm Corp., 747 F.2d 358, 364 (6th Cir. 1984)); First Nationwide Bank v. Nationwide Sav. and Loan Ass'n, 682 F. Supp. 965, 977 (E.D. Ark. 1988) (same). Here, no amount of consumer sophistication can overcome the identical nature of the two impactors.

Supp. 2d 86, 101 (D.P.R. 2003) (noting that courts infer wrongful intent where the parties have had a previous business relationship). When viewed in its full context, the extent of Westech's misconduct is extraordinary.

While MSP need not prove actual confusion when challenging a product that has recently been launched, evidence of actual confusion exists. See, e.g., Aveda, 706 F. Supp. at 1430 (D. Minn. 1989) (finding likelihood of success on the merits with no evidence of actual confusion because the infringing product was marketed only recently); Advantus Capital Mgmt., Inc. v. Aetna, Inc., No. 06-CV-2855, 2006 WL 2916840, *5 (D. Minn. Oct. 11, 2006) (holding that courts should not wait for actual consumer confusion to enjoin imitation products likely to mislead). Consumers have already questioned whether Westech is selling the real NGI device as an authorized distributor. Lanz Dec'l at ¶ 11; Roberts Aff. at ¶ 22.[5]

2. Westech Has Infringed MSP's Trade Dress

To demonstrate trade dress infringement, MSP must show that:

[5] See also, TCPIP Holding Co. v. Haar Commc'ns., Inc., 244 F.3d 88, 102 (2d Cir. 2001) (where defendant "has not yet launched its [products] in a serious way, there has been little or no opportunity for actual confusion to be manifested[,] ... [so] the absence of evidence of actual confusion sheds no light whatever on the problem"); Lois Sportswear, U.S.A., Inc. v. Levi Strauss & Co., 799 F.2d 867, 875 (2d Cir. 1986) (where accused infringer's sales were "minimal in the United States thus far" and there had been little chance for actual confusion, "[i]t would be unfair to penalize appellee for acting to protect its trademark rights before serious damage has occurred"); Kadant, Inc. v. Seeley Machine, Inc., 244 F. Supp. 2d 19, 31 (N.D.N.Y. 2003) (citations omitted) (no evidence of actual confusion necessary when product only developed and marketed for a few months).

> 1) the trade dress is non-functional; 2) the trade dress is either inherently distinctive or has acquired secondary meaning; and 3) defendant's use of the same or similar features (or combination of features) creates a likelihood of confusion in the consumer's mind as to the source of the product.

Empi, Inc. v. Iomed, Inc., 923 F. Supp. 1159 (D. Minn. 1996). Each of these considerations support the conclusion that Westech's wholesale copying of the NGI device infringes MSP's trade dress.

The external shape and color of the NGI device have no functionality whatsoever and are instead arbitrary embellishments used to identify the product. See Insty*Bit, Inc., 95 F.3d at 673 (holding that trade dress is nonfunctional when serving solely to distinguish the product). The non-functionality of the royal-blue and chrome color scheme is obvious—MSP could have chosen any color combination for the device. Similarly, the NGI device could have many shapes. Machining the unique puzzle-piece shape requires a detailed step in the manufacturing process that has no impact on the device's performance. MSP could have selected any number of other shapes. For example, a rectangular block would simplify the manufacturing process while having no impact on functionality. See Roberts Aff. at ¶ 15; Ex. 10. Because no functional purpose is served by the external shape or color scheme of the NGI device, these design features constitute protected trade dress. See Stuart Hall Co. v. Ampad Corp., 51 F.3d 780, 788 (8th Cir. 1995) (holding that trade dress includes product's "design and shape"); Prufrock Ltd., Inc. v. Lasater, 781 F.2d 129, 132 (8th Cir. 1986) ("The trade dress of a product 'involves the total image of a product and may include features such as size, shape, color or color combinations, texture, graphics, or even particular sales techniques.'"); Empi,

Inc., 923 F. Supp. at 1164 (recognizing shape of device as trade dress because no competitive purpose served by shape and alternative shapes could have fulfilled product's purpose).

Because the shape and color scheme of the NGI device are inherently distinctive characteristics that are not "dictated by the nature of the product," no further evidence is necessary to support entry of a preliminary injunction. See Stuart Hall Co., 51 F.3d at 785-86 (reversing denial of preliminary injunction because district court required proof of actual confusion to find inherent distinctiveness of trade dress).[6]

Even assuming, *arguendo*, that the NGI device's appearance is not inherently distinctive, it still constitutes protected trade dress because it has acquired secondary meaning. Secondary meaning is established when consumers associate trade dress with the origin or source of the product. Not only has NGI shown secondary meaning, see Roberts Aff. at ¶ 16; Miller Dec'l at ¶ 9; Lanz Dec'l at ¶ 7, Westech's copying compels a finding of secondary meaning. See, e.g., Empi, Inc., 923 F. Supp. at 1164-65 (relying on evidence of defendant's "intentional copying" and plaintiff's history of promoting a product with a unique look to find secondary meaning, even where survey data regarding actual association was rejected).

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[6] A unique, unusual, or unexpected product shape renders trade dress inherently distinctive. Id. at 786; Intsy*Bit, Inc., 95 F.3d at 673. "Fanciful" trade dress refers to design features that are "inherently distinctive and are entitled to protection" because "their intrinsic nature serves to identify a particular source of a product." Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 768 (1992). The puzzle-piece shape of the

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Westech's impactor is likely to confuse consumers for the reasons set forth above. See Section II.A.; Empi, Inc., 923 F. Supp. at 1166 ("Likelihood of confusion is evaluated in the same manner in trade dress cases as it is in trademark cases."). Hence, MSP will prevail on its claim for trade dress infringement.

3. Westech Has Falsely Advertised Its Impactor

False statements made to promote or advertise products violate the Lanham Act. To establish liability for false advertising under the Lanham Act, plaintiffs must show:

> (1) that the defendant made a false statement of fact about its product in a commercial advertisement; (2) that the statement actually deceived or has a tendency to deceive a substantial segment of its audience; (3) the deception is likely to influence the purchasing decision; (4) the defendant caused the false statement to enter interstate commerce; and (5) the plaintiffs have been or are likely to be injured as a result.

Blue Dane Simmental Corp. v. Am. Simmental Ass'n, 178 F.3d 1035, 1042 (8th Cir. 1999).

Westech makes literally false statements in its marketing literature. Literally false advertisements warrant an injunction whether or not the record contains evidence of actual consumer confusion. United Indus. Corp. v. Clorox Co., 140 F.3d 1175, 1180 (8th Cir. 1998). Accordingly, the Court need only determine whether Westech's advertisements convey an explicit message and whether that message is false. See, e.g.,

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NGI device is a textbook example of such a fanciful design created solely to distinguish and identify the product. See Roberts Aff. at ¶ 15.

Surdyk's Liquor, Inc. v. MGM Liquor Stores, Inc., 83 F. Supp. 2d 1016, 1022 (D. Minn. 2000).

Westech's advertising has included the following website page:

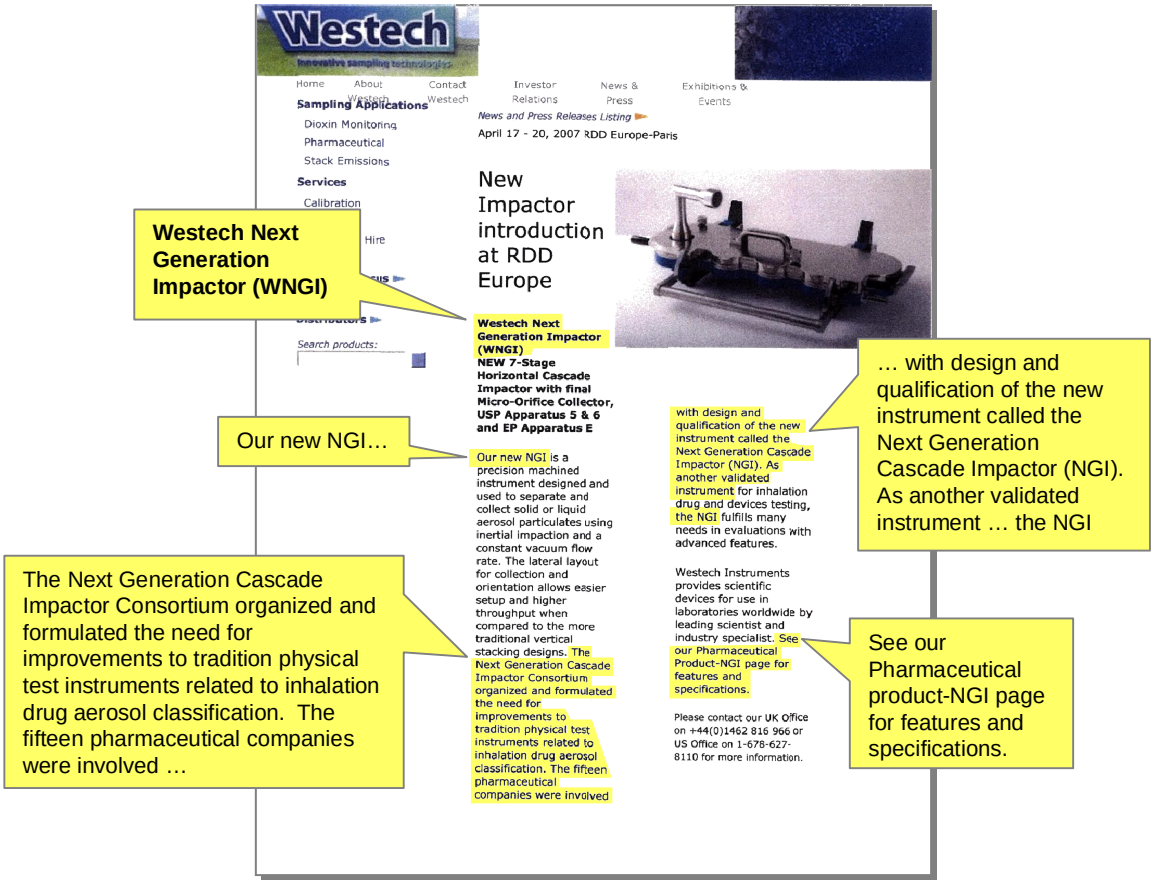

FIG. 5

Ex. 13. Referring to the imitation impactor that it calls "our NGI," Westech explicitly claims that,

> The fifteen pharmaceutical companies were involved with design and qualification of the new instrument called the Next Generation Cascade Impactor (NGI). As another validated instrument for inhalation drug and devices testing, the NGI fulfills many needs in evaluations with advanced features.

Id. This is false. The fifteen pharmaceutical companies were not involved with the design and qualification of the Westech impactor, nor was the Westech impactor "validated" by the Consortium. In fact, the Consortium no longer exists and could not possibly have had any involvement in the development of Westech's device. Moreover, the very description of the Westech impactor as the "Next Generation Impactor" and an "NGI" is literally false because there is only one genuine NGI that has been approved by the Consortium: MSP's product.

Westech has made other statements that are literally false by implication. A statement may be literally false by implication if the intended audience would recognize the claim "as readily as if it had been explicitly stated." Millennium Imp. Co. v. Sidney Frank Importing Co., 72 U.S.P.Q.2d 1661, 2004 U.S. Dist. LEXIS 11871 (D. Minn. 2004) (analyzing plaintiff's claim of literal falsity by necessary implication). See also Medtox Sci., Inc. v. Tamarac Med., Inc., No. 06-3546, 2007 U.S. Dist. LEXIS 314 (D. Minn. Jan. 4, 2007) (granting preliminary injunction on Lanham act false advertising claim when defendant's product label was literally false by necessary implication); Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co., 290 F.3d 578, 586 (3d Cir. 2002) (a message is false by necessary implication "when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated"); Scotts Co. v. United Indus. Corp., 315 F.3d 264, 274 (4th Cir. 2002) (same); Clorox Co. Puerto Rico v. Proctor & Gamble Commercial Co., 228 F.3d 24, 34 (1st Cir. 2000) (same).

Westech has partially altered the language currently on its website and in product brochures to make the misrepresentation of an endorsement by the Consortium less overt. Ex. 14 and 16. Consumers, however, will inevitably continue to read the current Westech website to assert that the Consortium assisted with the design of the Westech impactor and approved it. That message is conveyed as though it had been explicitly stated. The juxtaposition of information about the Consortium with the description of the Westech impactor would cause even a sophisticated consumer to read such statements as necessarily stating that the Westech impactor was developed in conjunction with, and approved by, the Consortium. See Medtox, 2007 U.S. Dist. LEXIS 314 at *9-10.[7]

Sealing the point, when listing the purported specifications of the Westech impactor in its product brochure, Westech actually cites to the peer-reviewed article, co-authored by one of NGI's founders, describing test results from MSP's NGI device. Ex. 14 at 14-2. Westech had the audacity to inform consumers that its imitation device has been validated by research conducted by MSP on the real NGI device, prior to the existence of Westech's imitation. See Ex. 5.

Westech's misrepresentations are yet another act of deception designed to misappropriate the history and reputation of the NGI device. As such, the misstatements

[7] Medtox is directly on point. In that case, this Court reviewed a label reading "D-Lead Soap and D-Wipe Towels are technology licensed to Tamarac Medical. They cannot be used with any other capillary blood lead test. U.S. patent applied for." The Court held that this statement was literally false by necessary implication because "even a sophisticated consumer audience" could read such statements to necessarily imply that

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are calculated to mislead consumers and influence their purchasing decisions. Impactor customers highly value the rigorous testing and approval process applied to the NGI device, and its broad acceptance throughout the industry has established the NGI device as the measurement standard. That is precisely the advantage of the NGI device that Westech is attempting to usurp in its advertisements. Lanz Dec'l at ¶¶ 4-5; Miller Dec'l at ¶¶ 6-7. Because many customers have no basis to question Westech's false invocation of the Consortium mantle, Westech's falsehoods have a substantial risk of inducing consumers to mistakenly purchase their imitation.[8]

Westech is trading on MSP's reputation and good name by falsely marketing a direct competitor to the NGI device, so MSP is likely to suffer injury. A preliminary injunction is necessary to preclude Westech from repeating its explicitly false statements to MSP's detriment.

B. WESTECH'S CONDUCT HAS IRREPARABLY INJURED MSP

Trademark infringement threatens the victim with irreparable harm and therefore justifies a preliminary injunction:

> "Irreparable harm exists, as a matter of law, where there is trademark infringement." *Minnesota Mining & Mfg. Co. v. Taylor*,

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Tamarac's rights were protected by the patent application rather than by a license agreement). Medtox, 2007 U.S. Dist. LEXIS 314 at *9-10.

[8] Westech cannot seriously dispute any of the remaining Lanham Act considerations. Its promotional materials have been posted on the Internet, and it is actively marketing the device in the United States. As a result, its false advertisements have been made in interstate commerce. See Intermatic, Inc. v. Toeppen, 947 F. Supp. 1227, 1239-40 (N.D. Ill. 1996).

> 21 F. Supp. 2d. 1003, 1005 (D. Minn. 1998). Thus, courts may presume irreparable harm when likelihood of confusion is demonstrated in a trademark case. *General Mills, Inc. v. Kellogg Co.*, 824 F.2d 622, 625 (8th Cir. 1987). Moreover, the loss of goodwill toward a business is precisely the sort of irreparable harm that is properly prevented through a preliminary injunction.

Advantus Capital Mgmt., Inc., 2006 WL 2916840 at *5. See also C&A Pro, LLC v. Pride Solutions, LLC, No. 04-3994, 2005 WL 388602, *6 (D. Minn. Jan. 17, 2005) ("A trademark represents intangible assets such as reputation and goodwill, which are irreparably harmed by consumer confusion as to the origin of the mark.") (internal quotation marks omitted) (citing General Mills, Inc. v. Kellogg Co., 824 F.2d 622, 625 (8th Cir.1987)).

The same presumption of irreparable harm applies to trade dress infringement and false advertising. See United Indus., 140 F.3d at 1183 ("When injunctive relief is sought under the Lanham Act, the finding of a tendency to deceive satisfies the requisite showing of irreparable harm."); Iomed, 923 F. Supp. at 1169 (presumption of irreparable harm from trade dress infringement).

Westech's scheme of infringement and deception has been planned to capitalize on the hard work and reputation represented by the MSP's marks and trade dress. Westech's usurpation of MSP's good will and reputation is compounded by the risk that Westech will undermine the NGI device's status as the standard for reliable, uniform measurement of inhaler aerosols if left unchecked. A preliminary injunction is necessary to prevent the irreparable injury that Westech's misconduct will inevitably cause.

C. THE BALANCE OF HARMS SUPPORTS ENTRY OF AN INJUNCTION

Once a plaintiff has demonstrated a likelihood of prevailing on a claim of trademark or trade dress infringement, the balance of harms favors the plaintiff. Aveda, 706 F. Supp. at 1431. Additionally, this Court favors the market incumbent because the party that has invested time, resources, and reputation to develop a product and its accompanying marks should be protected from newcomers using shortcuts to capitalize on that hard work and good will. Advantus Capital Mgmt., Inc., 2006 WL 2916840 at *6. Finally, defendants who have only recently marketed a competing product do not weigh heavily in the balance of harms. See Aveda, 706 F. Supp. at 1431 (protecting established product over recent entrant).

MSP is the party that stands to lose its reputation absent an injunction. Westech should not be allowed to introduce a knockoff product and falsely portray it as the original or as approved by MSP or the Consortium.

D. THE PUBLIC INTEREST SUPPORTS ENTRY OF AN INJUNCTION

The public interest supports a preliminary injunction prohibiting Westech from infringing MSP's trademarks and trade dress and making false and misleading claims. See Am. Dairy Queen Corp. v. New Line Prods., Inc., 35 F. Supp. 2d 727, 733 (D. Minn. 1998) ("Infringement and dilution of trademarks are inherently contrary to the public interest."). Once plaintiffs have established a likelihood of confusion, the public interest supports an injunction to protect consumers. Aveda, 706 F. Supp. at 1432 (trademark); Iomed, 923 F. Supp. at 1170 (trade dress).

The public interest requires that the Court put an end to Westech's deception. A buyer who mistakenly purchases a potentially unreliable device from Westech can suffer severe harm by having measurement data invalidated or questioned by regulators. Westech also threatens to undermine years of work by the Consortium and MSP to develop a uniform, reliable method for measuring inhaler dosages. Circulation in commerce of an unreliable, yet visually indistinguishable, version of the NGI device has the potential to destroy the confidence that regulators and the industry have placed in the real NGI. Everyone from pharmaceutical companies to patients waiting to benefit from the development of new inhaled medicines has been put at risk by Westech's irresponsible conduct.

IV. CONCLUSION

For the foregoing reasons, MSP respectfully requests entry of a preliminary injunction in the form submitted to the Court.

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